Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

Mountain-Pacific Quality Health

It’s Worth a Shot

Updates About the COVID-19 Vaccine Mandate

February 16, 2022

Housekeeping Items

- Add your webinar topics and clinician ideas or needs into chat!
- We will meet every Wednesday through April 13, 2022!

Emergency Use Authorization (EUA)

https://www.youtube.com/watch?v=iGkwaESsGBQ&t=105s

Visit the U.S. Food & Drug Administration for information about emergency use authorization: www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

Outpatient COVID-19 Therapies

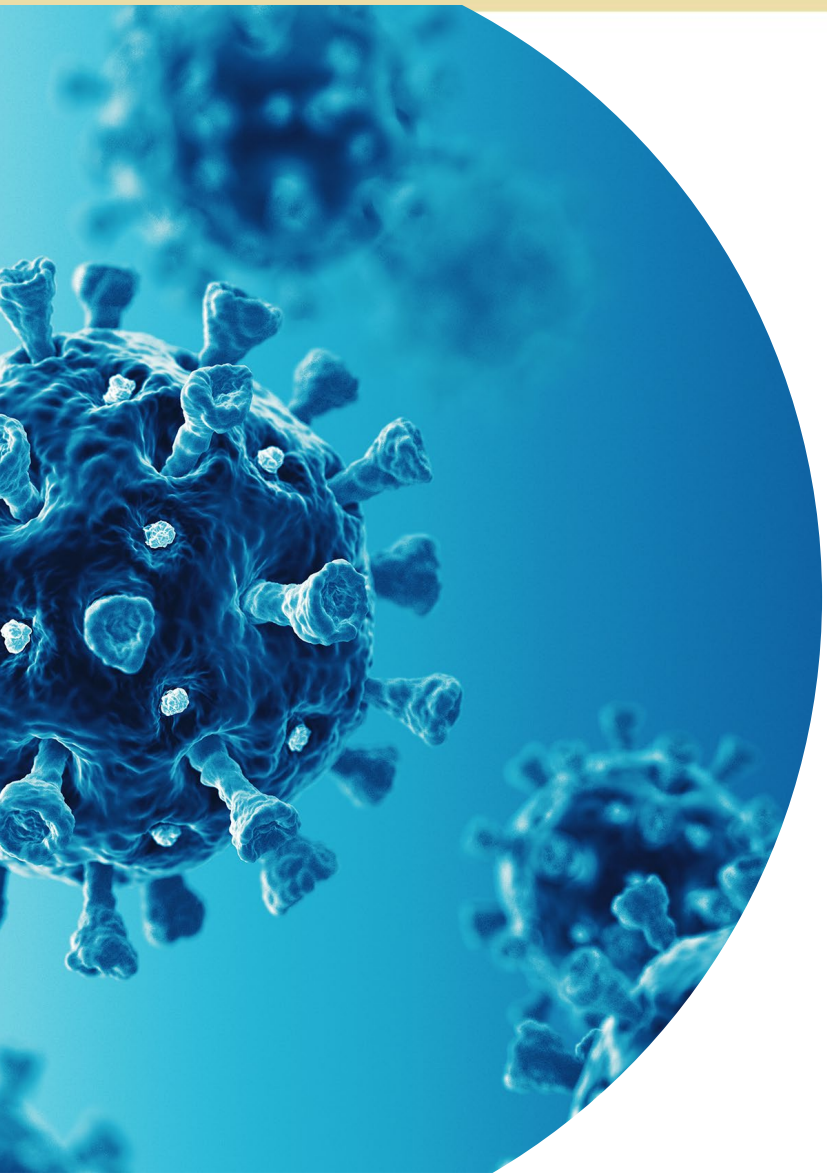
	Paxlovid (Pfizer)	Sotrovimab (GlaxoSmithKline)	Remdesivir (Gilead)	Molnupiravir (Merck)
Age eligibility	12+	12+	All	18+
Initiate within number days of symptom onset	< 5 days	< 10 days	< 7 days	< 5 days
Mechanism of action	Viral protease inhibitor that halts viral replication	Monoclonal antibody against spike protein; blocks viral entry	Nucleoside analog that halts viral replication	Nucleoside analog that inhibits viral replication by viral mutagenesis
Route of administration	Oral	IV	IV	Oral
Duration of treatment	Five days	One infusion	Three infusions over three days	Five days

Source: https://dhss.alaska.gov/dph/Epi/id/Pages/COVID-19/therapeutics.aspx

Nirmatrelvir/ritonavir (Paxlovid)

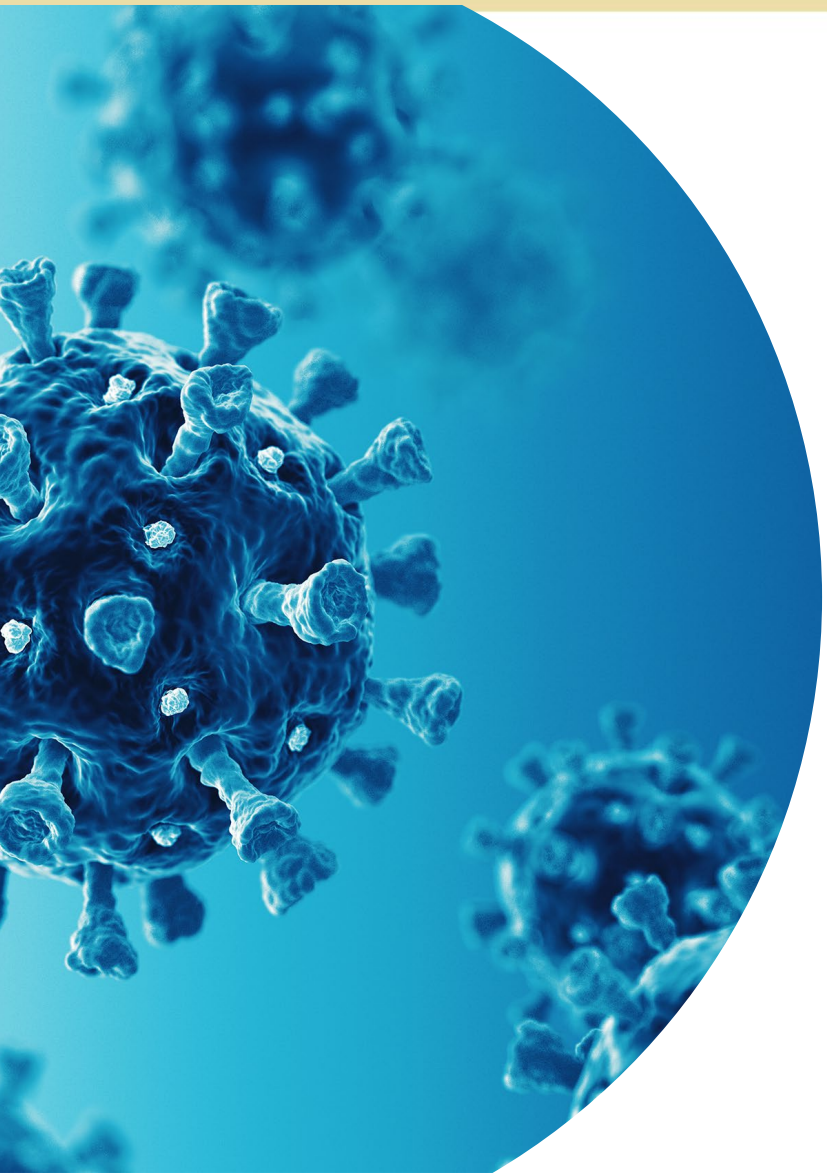
- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir orally twice daily for 5 days
- Adjustment for renal impairment
  - moderate renal impairment (eGFR ≥30 to <60 mL/min), the dosage is 150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days
  - Not recommended in patients with severe renal impairment (eGFR <30 mL/min)
- Hepatic Impairment
  - Not recommended for use in patients with severe hepatic impairment (Child-Pugh Class C)
- Contraindicated with drugs that are highly dependent on CYP3A
  - Side effects: altered sense of taste, diarrhea, high blood pressure, muscle aches

Molnupiravir



- 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food
- No dosing adjustment for renal or hepatic impairment
- Not recommended in pregnancy or breastfeeding
- Side effects
    - diarrhea, nausea, and dizziness

Monoclonal Antibodies

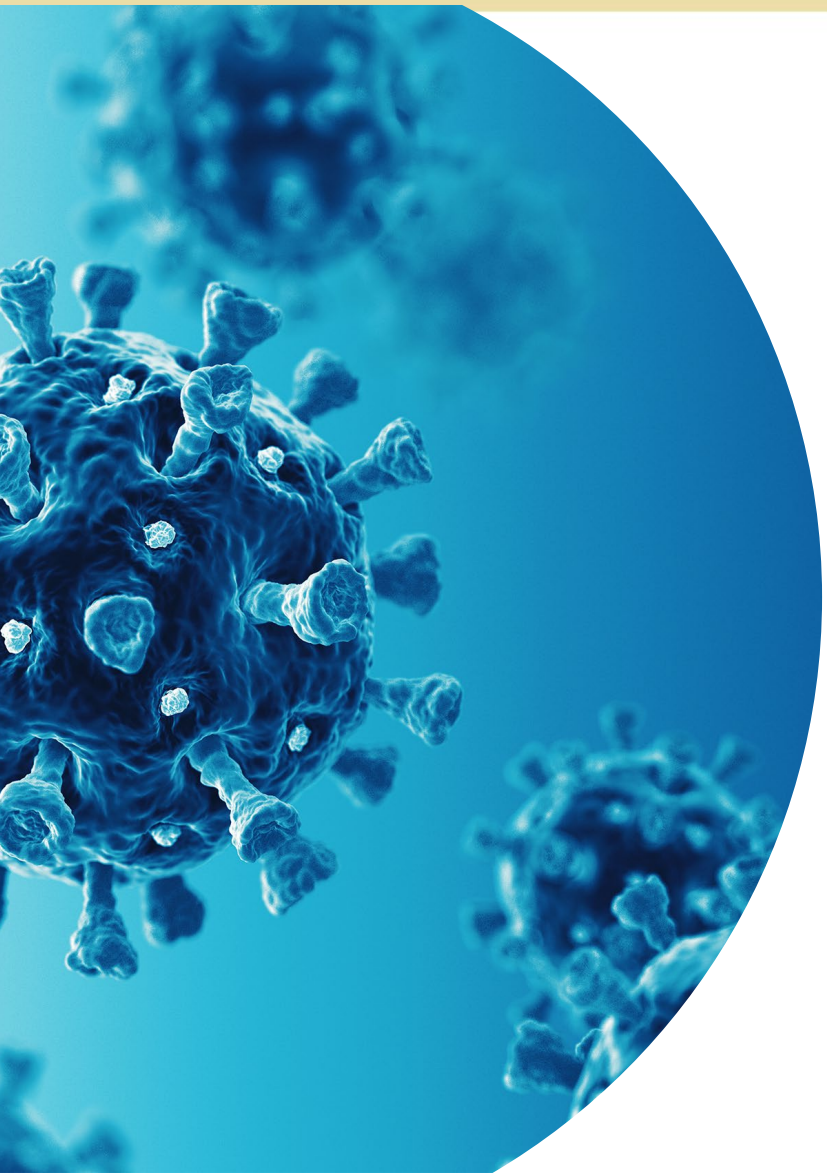


Sotrovimab

- Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing **and**
- Who are at **high risk** for progression to severe COVID-19, including hospitalization or death

Source: https://www.fda.gov/media/149534/download

Monoclonal Antibodies

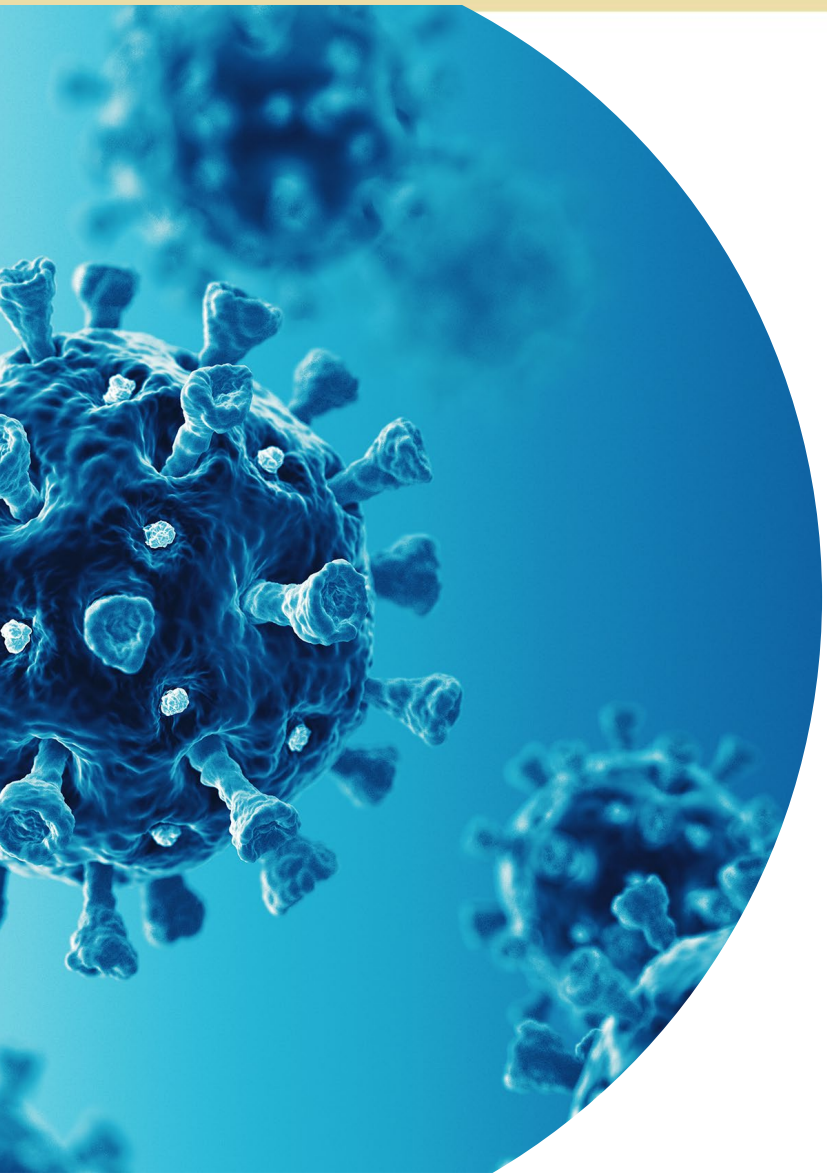


Bebtelovimab—approved February 11, 2022

- With positive results of direct SARS-CoV-2 viral testing **and**
- Who are at **high risk** for progression to severe COVID-19, including hospitalization or death, **and**
- For whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.

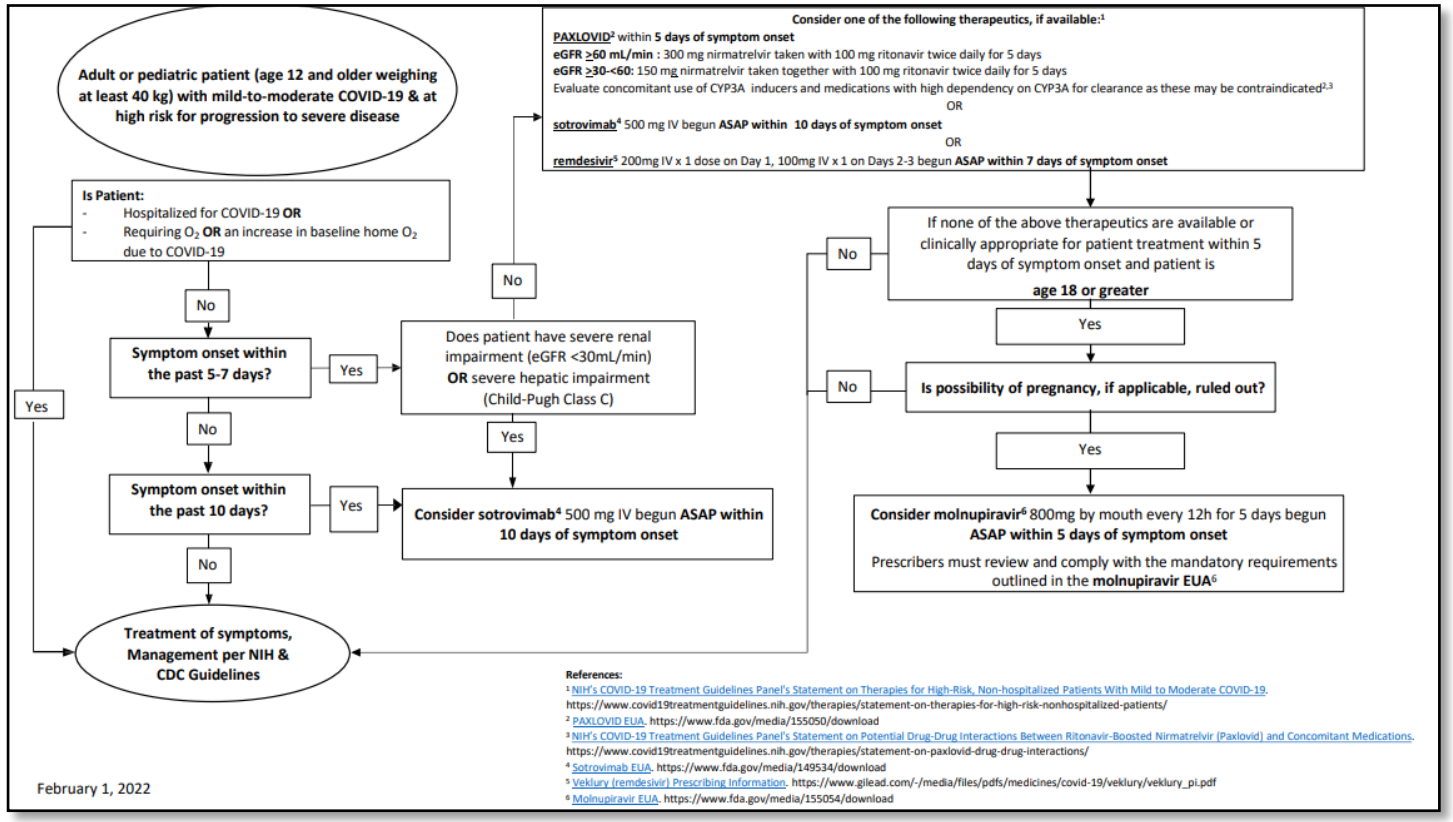
Source: https://www.fda.gov/media/156152/download

Veklury (Remdesivir)



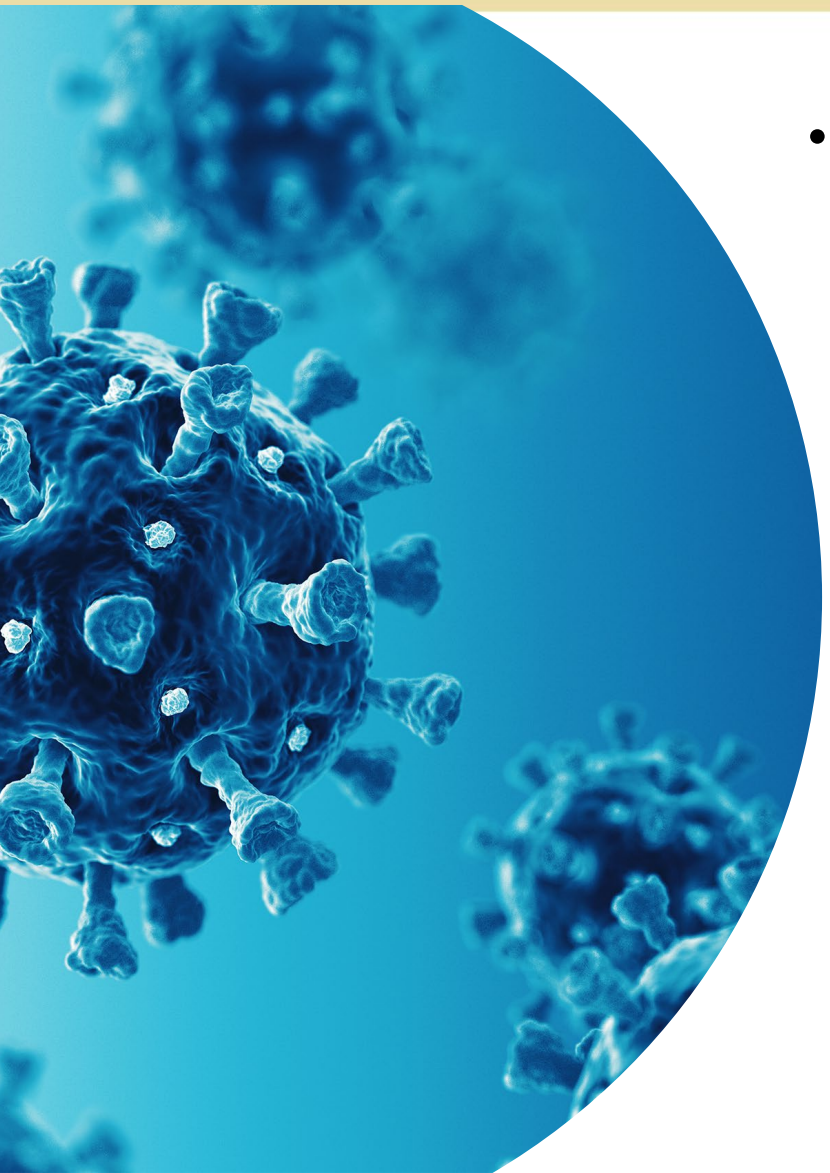
- Treatment of coronavirus disease 2019 (COVID-19) in pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg, with positive results of direct severe acute respiratory syndrome coronavirus 2 SARS-CoV-2) viral testing who are
- Hospitalized **or**
- Not hospitalized and have mild-to-moderate COVID-19, and are at **high risk** for progression to severe COVID-19, including hospitalization or death

Therapeutics Decision Tree



View a larger version by visiting:
www.phe.gov/emergency/events/COVID19/therapeutics/Documents/COVID-Therapeutics-Decision-Aid.pdf

EVUSHELD (tixagevimab/cilgavimab)



- Intramuscular injections as **pre-exposure prophylaxis** for adults and adolescents who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, **AND** who:
    1. Are moderately to severely immunocompromised and may have inadequate immune response to COVID-19 vaccination ***or***
    2. Are not able to be fully vaccinated with any available COVID-19 vaccines due to a documented history of severe adverse reaction to a COVID-19 vaccine or any of its components

Source: www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/

Resources

- **Treatment Guidelines Panel's Statement on Therapies for High-Risk, Nonhospitalized Patients With Mild to Moderate COVID-19:** https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/
- **IDSA guidelines:** https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/
- **Paxlovid EUA:** https://www.fda.gov/media/155050/download
- **Remdesivir EUA:** https://www.fda.gov/media/137566/download
- **Molnupiravir EUA:** https://www.fda.gov/media/155054/download
- **Sotrovimab EUA:** https://www.fda.gov/media/149534/download
- **EVUSHELD EUA:** https://www.fda.gov/media/154701/download
- **Bebtelovimab EUA:** https://www.fda.gov/media/156152/download
- **FDA full list of EUA Drugs and Non-Vaccine Biological Products:** https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs
- **Therapeutics Finder:** https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/
- **Being moderately to severely immunocompromised** https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html
- **High-risk conditions** https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Vaccine Accessibility

State Vaccine Provider Programs

- Enrollment requirements:
  - Storage unit and temperature monitoring capabilities **meet minimum CDC standards**
  - Medical licenses for prescribing providers listed on the provider agreement are current
  - Necessary information for vaccine distribution system
  - Staff training
  - Program management plan

Vaccine Accessibility

State Vaccine Provider Programs

Inventory management
- Minimum Order Quantities
- Transfer ability

Storage and expiration tracking
- Administration, waste, inventory, reconciliation, ordering

Training/dedicated staff

Reviewing our Options

Direct Order Breakdown

Vaccine	Direct Minimum Order Size	# Vials per Shipment	Refrigeration Storage Time 2°C and 8°C (36°F and 46°F)	Freezer Storage Time -50°C and -15°C (-58°F and 5°F)	Usage Breakdown
Pfizer Ped (orange cap)	100 doses	10	10 weeks	N/A	One vial per week
Pfizer Adol/Adult (grey cap)	300 doses	50	10 weeks	N/A	One vial per business day
Moderna	100 doses	10	30 days	Until Expiration (at least 3 months)	Refrigerated: ~3 vials per week Freezer and Refrigerated: ~3 vials per month

Reviewing Our Options

Connecting our Resources

- State immunization departments
- Local health departments
    - Federally Qualified Health Centers (FQHC)
- Hospitals
- Pharmacies

Resources

Wyoming Immunization Unit:
https://health.wyo.gov/publichealth/immunization/immunization-provider-resources/public-vaccine-programs/
COVID-19 Vaccine Information: 800-438-5795 (Weekdays 8am-5pm)
Holly.scheer@wyo.gov

Alaska Immunization Unit:
https://dhss.alaska.gov/dph/epi/id/pages/covid-19/vaccineproviders.aspx
Immunization Program Manager matthew.bobo@alaska.gov

Montana Immunization Unit:
https://dphhs.mt.gov/publichealth/immunization/
Adult Immunization Coordinator trisha.gardner@mt.gov

Hawaii Immunization Unit:
doh.covid-enrollment@doh.hawaii.gov
Immunization Branch at (808)586-8332 or (833)711-0645

Quality Improvement Organizations
Sharing Knowledge. Improving Health Care.
CENTERS FOR MEDICARE & MEDICAID SERVICES

Mountain-Pacific Quality Health

Thank you!

Join us next week on
Wednesday, February 23, 2022.

This material was prepared by Mountain-Pacific Quality Health, a Medicare Quality Innovation Network-Quality Improvement Organization (QIN-QIO), under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services (HHS). Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS. 12SOW-MPQHF-AS-NH-02/22-109